DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

3VIA FEDERAL EXPRESS
Our Reference: 3003806302

August 7, 2003

Ronald J. Pezzolo, Owner
Pezzolo Seafood
Pier 45 Shed D
San Francisco, California 94133

WARNING LETTER

Dear Mr. Pezzolo:

On May 13, 15, and 19, 2003, we inspected your seafood processing facility, located at Pier 45 Shed D, San Francisco, CA. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly your Dungeness crabs are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health:

You may find the Act and the Seafood HACCP Regulation through links in FDA's home page at www.fda.gov.

We acknowledge receipt of your letter dated June 5, 2003 including copies of your revised Cooked Crab Procedures, revised Hazard Analysis Worksheet, revised HACCP Plan, Dungeness Crab Cooking Log, Sanitation Report, and Daily Maintenance Guidelines.

The deviations based on the inspection and your letter of June 5, 2003 are as follows:

1. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any of the critical control points (receiving, cooling, storage, cooking, and cooling) to control pathogen growth listed in your HACCP plan for Cooked Dungeness Crabs. We acknowledge that your letter of June 5,

2003 includes a Dungeness Crab Cooking Log in which you indicate your intent to record monitoring observations at the cooking and cooling after cooking critical control points. However, you must also record monitoring observations at the receiving, cooling, and storage critical control points.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as the "maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for Cooked Dungeness Crabs lists a critical limit, "[redacted] at the cooling critical control point that is not adequate to control pathogen growth. FDA recommends that you refer to the Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, Chapter 12, for more information on cooling after cooking.

   The critical limits in your revised HACCP plan are stated as "[redacted], 2) Store at [redacted] degrees." We believe these revised critical limits are inadequate since they do not identify the time it takes for the product to cool from 70° F to 40° F. The product should generally be cooled to 70° F or below within two hours and to 40° F or below within another four hours to control the hazard of pathogen growth and toxin formation when there is no significant handling.

3. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6 (c) (4). However, your firm's HACCP plan for Cooked Dungeness Crabs lists a monitoring frequency at the finished product storage critical control point that is not adequate to control the food safety hazard of pathogen growth and toxin formation. FDA recommends continuous monitoring by the instrument itself, with a visual check of the instrument at least once per day. If the product is stored under ice or chemical cooling media, an alternative monitoring procedure would be visual observation of the adequacy of the ice at least twice per day or for finished product storage, at least immediately prior to shipment.

4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm failed to prevent cross-contamination from insanitary objects to food, food packaging material, and other food contact surfaces as evidenced by our investigator observing employees handling wooden pallets and other surfaces and then packing cooked, ready-to-eat crabs without washing or sanitizing their gloves.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is

not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulation, and the Current Good Manufacturing Practice regulation (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District

Enclosure:
Form FDA 483